

**SickKids Master CHSS Data Transfer Agreement (“Agreement”)
Research Use of Personal Health Information**

BETWEEN:

AND

<p>The Hospital for Sick Children (“SickKids”) 555 University Avenue Toronto, ON, M5G 1X8, Canada</p>	<p>XXXXX (“Provider Institution”) [Insert name of organization and address for legal purposes]</p>
<p>SickKids Investigator(s):</p> <p>Dr. William G. Williams Dr. Christopher A. Caldarone Dr. Brian W. McCrindle</p> <p>(SickKids and SickKids Investigators are together, “CHSS Data Center”)</p>	<p>Provider Investigator(s):</p> <p>Dr. _____</p> <p>(Provider Institution and Provider Investigator are together “PROVIDER”)</p>
<p>CHSS Data Center’s Managing Director:</p> <p>Dr. William M. DeCampi</p>	

WHEREAS SickKids Investigator and Provider Investigator are members of the Congenital Heart Surgeons’ Society (“CHSS”); and the CHSS Data Center is the coordinating site for CHSS studies involving the collection and analysis of data from CHSS members;

AND WHEREAS this Agreement shall govern the transfer of data for all CHSS studies which PROVIDER participates in (“CHSS Study/Studies”);

AND WHEREAS this Agreement shall be applicable to SickKids and the Provider Institution with respect to all CHSS Studies; and shall be applicable, with respect to each CHSS Study, to that SickKids Investigator and Provider Investigator identified as the principal investigator at his/her respective institution for that CHSS Study;

AND WHEREAS the SickKids Investigators and Provider Investigator(s) listed above are those who are anticipated to act as a principal investigator at SickKids and PROVIDER, respectively, for CHSS Studies;

NOW THEREFORE, the parties hereto agree as follows:

1. “Data” shall mean the data to be transferred from the PROVIDER to the CHSS Data Center as per the applicable REB/IRB approved protocol for the subject CHSS Study (“Protocol”), in accordance with each Study subject’s informed consent and authorization required by the Health Insurance Portability and Accountability Act (the “HIPAA Authorization”). Each such Protocol is incorporated herein by reference.
2. If an investigator not listed above is acting as the principal investigator at SickKids or PROVIDER with respect to any CHSS Study, such investigator must first sign the Rider attached hereto as Appendix A before participating in such CHSS Study.
3. CHSS Data Center and PROVIDER acknowledge that: (1) the Data will contain personally identifiable information/protected health information (collectively, “PHI”) about Study subjects from whom the Data was collected, and is therefore protected by law; and (2) in accordance with the Protocol, the Study subject’s informed consent, and the Study subject’s HIPAA Authorization, the

CHSS Data Center may be using the Data to directly contact individuals from whom the Data was collected to perform follow-up as part of the CHSS Study.

4. PROVIDER will prepare and furnish the Data to CHSS Data Center in accordance with applicable laws and regulations, and specifically warrants that transfer of the Data by PROVIDER for use in accordance with the Protocol and this Agreement will be in compliance with PROVIDER's REB/IRB approved subject informed consent forms ("ICFs") provided by the individuals from whom the Data was collected, or terms of PROVIDER's REB/IRB waiver of consent ("Waiver"), as applicable, which shall explicitly permit the Data to be used by the CHSS Data Center as set out in the Protocol, and specifically as set out in section 3 herein. Data will not be transferred until each party's IRB/REB provides written approval for the subject CHSS Study.
5. Prior to transferring Data for a CHSS Study to the CHSS Data Center, PROVIDER shall provide CHSS Data Center with a copy of the HIPAA Authorization and/or approved ICF or Waiver, as applicable, for the subject CHSS Study.
6. PROVIDER retains ownership of its Data provided under this Agreement.
7. CHSS Data Center shall use the Data in compliance with all applicable laws and regulations; and shall specifically only use or disclose the Data for the conduct of the subject CHSS Study for which the Data was transferred, in accordance with the permitted uses of the Data specified in the applicable ICFs or Waiver as set out above, or otherwise as required by law. CHSS Data Center shall ensure that all Data is maintained in a secure form and location.
8. CHSS Data Center shall have the right to use de-identified information and results derived from use and analysis of the Data as part of a publication or presentation of the results of the CHSS Study, and shall own such de-identified, analyzed data and results. It is the intention of the parties that the results of each CHSS Study will be published in accordance with CHSS publication protocols.
9. Data is "de-identified" if it does not identify an individual and if there is no reasonable basis to believe it could be used alone, or with other available information, to identify an individual. CHSS Data Center shall not include any personally identifying information in any publication or presentation, or any other disclosure to a third party, except as set out in the Protocol and this Agreement, or as required by law.
10. CHSS Data Center shall use appropriate safeguards to prevent any unauthorized use or disclosure of the Data and shall promptly report to the PROVIDER any unauthorized use or disclosure of which CHSS Data Center becomes aware, or of any breach of this Agreement.
11. Upon completion or termination of the applicable CHSS Study, or upon written request from PROVIDER, CHSS Data Center shall return to PROVIDER, or securely destroy, as requested, the Data as received by the CHSS Data Center from PROVIDER in its raw form for that CHSS Study, subject to applicable law, including regulations regarding retention of study data. Secure destruction shall mean: (i) shredding or destroying paper, film, or other hard copy media to ensure that the Data cannot be read or otherwise reconstructed or (ii) clearing, purging or destroying electronic media such that the Data cannot be read or otherwise reconstructed, and providing written confirmation of such destruction to PROVIDER.
12. PROVIDER may, upon reasonable notice, arrange with CHSS Data Center to attend CHSS Data Center's site within normal business hours to conduct audits of the CHSS Data Center (no more frequently than once per calendar year) concerning the maintenance of appropriate security safeguards to ensure compliance with this Agreement.

13. CHSS Data Center shall give access to the Data only to those individuals with a need to know for the purpose of conducting the CHSS Study, including CHSS Data Center staff, study staff and collaborators, who are required by CHSS Data Center to comply with the terms of this Agreement.
14. Any legal action, claim or other legal proceeding commenced by one party hereto against another party, arising out of this Agreement, shall be commenced in the courts of the jurisdiction in which the responding party is situated; and for the purposes of such proceeding, this Agreement shall be governed by, and shall be interpreted, construed and enforced, in accordance with the laws of that same jurisdiction.

SICKKIDS	XXXXX – Insert Name of Organization
Signature:	Signature:
I have authority to bind the organization.	I have authority to bind the organization.
Date:	Date:
Name & Title:	Name & Title:
Dr. William G. Williams	Provider Investigator:
Signature:	Name: Dr. _____
Date:	Signature:
Dr. William M. DeCampi	Date:
Signature:	Provider Investigator: Name: Dr. _____
Date:	Signature:
Dr. Christopher A. Caldarone	Date:
Signature:	Provider Investigator: Name: Dr. _____
Date:	Signature:
	Date:
Dr. Brian W. McCrindle	
Signature:	
Date:	

APPENDIX A – RIDER

I, _____, am the principal investigator at _____ with respect to one or more CHSS Studies. I acknowledge that I have read and understood, and hereby agree to abide by, the terms of the SickKids CHSS Master Data Transfer Agreement to which this Rider constitutes Appendix A, with respect to each such CHSS Study that I am the principal investigator of.

Signed By:

Name:

Date: